US ERA ARCHIVE DOCUMENT

MRID # 402369-05

DATA EVALUATION RECORD

1. N-(phosphonomethyl) glycine CHEMICAL: Shaughnessey No. 103601.

TEST MATERIAL: Technical glyphosate, 96.6% a.i., Lot No. 2. NBP-3594465, CAS No. 1071-83-6, a white solid

Nontarget area phytotoxicity, aquatic plant STUDY TYPE: 3. growth - Lemna gibba.

CITATION: 4. Hughes, J.S. 1987. The Toxicity of Glyphosate Technical to Lemna gibba. Project No. 1092-02-1100-5. Prepared by Malcolm Pirnie, Inc. White Plains, NY. Submitted by Monsanto Agricultural Company, Chesterfield, MO. MRID No. 402369-05.

5. REVIEWED BY:

> Bruce A. Rabe Aquatic Toxicologist Hunter/ESE

6. APPROVED BY:

> Prapimpan Kosalwat, Ph.D. Staff Toxicologist KBN Engineering and Applied Sciences, Inc.

Henry Craven Supervisor, EEB/HED USEPA

Signature: Bucco a. Male

Signature: P. Kosalwat

Date: Dec. 6, 1988

Signature: Henry 1 Crown

Date: 1/9/96

This study appears scientifically sound. The 7. CONCLUSIONS: 7-day EC50 for Glyphosate Technical was 21.5 mg/L.

8. RECOMMENDATIONS: N/A

9. **BACKGROUND:**



10. DISCUSSION OF INDIVIDUAL TESTS: N/A

11. <u>MATERIALS AND METHODS</u>: A static assay test on <u>Lemna gibba</u>, obtained from stock cultures, was conducted by the laboratory of Malcolm Pirnie, White Plains, New York. The test was conducted for 14 days in a Sherer Model RI-32LLTP Incubator. Continuous illumination of 4198 - 5813 lumens/ m^2 was provided by warm-white fluorescent lights. Temperature was maintained at 25 \pm 2 °C.

Test bottles utilized were sterile 500-mL Erlenmeyer flasks fitted with foam stoppers. Three replicates were used for each treatment.

Nominal tests concentrations of 5, 9, 16, 28, and 50 mg/L were prepared by diluting appropriate volumes of a 2.5 mg a.i./mL stock solution to 200 mL volumes with sterile-filtered 20X-AAP medium. Test and control solutions were inoculated with Lemna sp. from a 7-day old stock culture by adding three four-frond colonies and one three-frond colony to each test vessel, for a total of 15 fronds per vessel.

Growth as measured by frond production was determined on test days 2, 4, 7, 9, 11, and 14 using a lighted magnifying lens. In order to eliminate subjective decisions on frond maturity, every frond visibly projecting beyond the edge of the parent frond was counted.

Samples were analyzed by Monsanto Company, Chesterfield, MO for actual concentrations of glyphosate on test days 0 and 7. Samples on day 0 before inoculation and samples passed through a 0.8 micron membrane filter on day 7 were placed in polyethylene bottles and frozen prior to shipment to Monsanto Company. Samples were analyzed by a high pressure liquid chromatograph (HPLC) equipped with an ophthalaldehyde (OPA) post-column reactor (PCR) and fluorescence detector.

The EC25 and EC50 values for glyphosate were calculated by plotting the log of average measured concentration (x-axis) against the percent inhibition expressed as probit (y-axis). Inverse estimation least squares linear regression was used to determine the line of best fit, the concentrations corresponding to 25 and 50 percent inhibition and associated 95% confidence limits. Parameters of the regression line were determined using the SAS statistical package. The values for the test concentrations that were stimulatory were omitted from the regression analysis.

12. <u>REPORTED RESULTS</u>: Mean standing crop (frond numbers) and Percent Inhibition, Relative to Control, for <u>Lemna gibba</u> Exposure to Glyphosate Technical

Mean Measured Percent Concentration ^a mg/L	Day 2	Day 4	l Day 7	Day 9	Day 11	Day 14	Inhib.	b
<0.05 (0)	31	65	169	286	442	665		
4.28 (5)	29	64	181	311	550	676	-1.8	0
9.02 (9)	28	61	182	325	536	688	-3.6	0
16.6 (16)	28	61	172	275	480	572	14.2	14
29.0 (28)	25	46	105	147	179	175	75.4	74
49.4 (50)	23	36	77	110	113	108	85.6	84

a The nominal concentrations are given in parentheses b The percent inhibition is based on day 14 values

13. STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:
Based on mean standing crop the 14-day EC25 was 18.0 mg/L
and the 14-day EC50 was 25.5 mg/L. The 95% confidence
limits for these EC values could not be determined from the
data since an error condition arises in the calculations as
a result of an attempt to take the square root of a negative
number. The measured concentrations on day 14 yielded an
average of 94.6% of the nominal concentrations.

The study was conducted following the intent of the Good Laboratory Practice Regulations and the final report was reviewed by Malcolm Pirnies' Quality Assurance Unit. A Quality Assurance Statement was included and signed by the Quality Assurance Officer.

REVIEWER'S DISCUSSION AND INTERPRETATION OF STUDY RESULTS: 14.

- Test Procedure: The procedures were generally in accordance with protocols recommended by the Guidelines, but deviated from the SEP as follows:
- The test medium pH was adjusted to 7.5 during medium preparation. The SEP states pH of the test medium should be approximately 5.0.
- The test was initiated with four Lemna gibba plants frond plants and one three-frond plant). The SEP states five Lemna gibba plants should be used.
- Statistical Analysis: The reviewer used linear regression analysis to calculate the EC25 and EC50 values of 13.0 mg/L and 21.5 mg/L, respectively. These calculations are attached. The calculated values are slightly lower then the reported values (i.e., EC25 18.0 mg/L and EC50 25.5). The reported values were calculated with the omission to the two stimulatory concentrations. This omission results in artificially high EC values. The reviewer believes that the EC25 and EC50 values calculated by linear regression are a more representative set of values because stimulatory as well as inhibitory values are included in the EC determinations.
- Discussion/Results: The study results appear to be scientifically valid. The 7-day EC50 value based upon measured concentrations was estimated to be 21.5 mg/L.
- D. Adequacy of the Study:
 - (to be added) CONE CRL 9/19/9/ (1) Classification:
 - (2) Rationale: N/A
 - Repairability: N/A (3)
- 15. Completion OF ONE-LINER FOR STUDY: Yes, 11-30-88

No	Chemical Name Glyphosate Chemical Class Face	<u> </u>	 _
Study/Species/Lab/		Reviewer/	Validation
Succession 4 a.i. 14-Day Single Dose Oral LD50	Pasults 95% C.L	Catos	Statis
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Species	Slope=		
Lab	14-Day Dose Cavel mg/kg/(% Mortality)		
Acc.	Commences		
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14-Day Single Dose Oral ${\rm LD}_{50}$	LD50 = mg/kg () Contr. Mort.(%)=		
Species	Slope=		
Lab	Sex = 14-Day Dose Level mg/kg/(% Mortality)		
Acc.	Connectes:		
8-Day Dietary LC50			
- 10 10 10 10 10 10 10 10 10 10 10 10 10	95% C.L.) Contr. Mort.(%)=		
Species	Slope=		
Lab	Sex *		-
	3-Day Cose Level con/(Mortality)		
Acc.	Comments:		•
8-Day Dietary LC ₅₀	95% C.L		
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•	Slope= + Animals/Level=		
Lab	96-Hour Dose Level on // Mortalian		
Acc	(), (), (),		
	Comments:		
14 7-day EC 50	Ecso = 21.5 pm (N/A) con. vor(3) = NA		
Species Lemna gibba	Sol. Com. Mor. (%) = NA		
96.6	N. A. 25120C	BAR 11/30/88	-
Lab Malcolm Pirnie	7-Day Dose Level ppm/% inhibition 4.28(1.8) 9.02(3.6)16.6(14.2)29.0(75.4)49.4(85.6)	11/ 50/00	
Acc. 40236905	Comments: Underlined Inhibition values are % stimula	ation	
96-Hour LC50	* = Mean measured concentration.		
	(C30 = pp_ ()		
Species	Sol. Comy More of 1) = Slope= 1 Animals/Lavels		•
Lab	Thing. #		
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